DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: NOV 12 2003

5157 '03 JAN 26 P2:02

From: Interdisciplinary Scientist/Pharmacist , Division of Dietary Supplement Programs , Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: VasoCleaner

Firm: PanVital, Inc.

Date Received by FDA: 1/22/03

90-Day Date: 4/23/03

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Gloria Chang

P drive/ NDI/ NDI File Closeout/DDSP SOP closeout process...

95S-0316

RPT 168

PanVital Inc **New York, NY 10032**
725 West 172 Street, #46
Fax: 212-928-0373
Phone: 617-359-6531

We understood that, the whole notification should be focused on the safety of the specific formulation, *VasoCleaner* ™. Although one part of the information we provided regarding the standards for each ingredient established by the pharmacopoeia of the People's Republic of China conveys general commentaries on the safety and function effects, we did include two sections in our notification, which are **Secion2**, the toxicological data and **Section 3**, the pharmacological data, to provide related information for the safety evaluation of this specific formulation.

We note that under your conditions of uses for the target population you reference the terms "Patients with atherosclerosis and/or hyperlipoproteinmia" and under the duration of use you use the terms "symptoms and diseases" and "for atherosclerosis patient" and "to hyperlipoproteinmia patients." Please be aware that under 21 U.S.C. 321(g)(1)(B), if a product is implicitly or expressly represented as being intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease, it may be subject to regulation under the drug provisions of the Act. Further, you can find information on claims that maybe made the labeling of dietary supplements pursuant to 21 U.S.C. 343(r) (6) in the final rule on struture/function claims published in the).

We are aware that the terms "Patients with atherosclerosis and/or hyperlipoproteinmia" are improper statement for the target population. Therefore, under the final rule of ***January 6, 2000 Federal Register(65FR 1000),*** we change the statement to "population who want to maintain healthy cholesterol levels". Furthermore, the statements of nutritional support read as follows:

"Help to keep cholesterol levels in a normal range"
"Maintain healthy cholesterol levels"

These statements will be accompanied by the required disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

In the previous notification, we want to keep following parts confidential:

1. All cover letters related to ingredients and the amount ratio of each ingredient in *VasoCleaner* ™
2. Section 4: Documents related to the Chinese Patent.

Again, we highly appreciate your consideration. Please contact me if you have any more questions concerning this matter.

Sincerely yours,

Yanzhu Liu
President
PanVita l Inc.

PanVital Inc **New York, NY 10032**
725 West 172 Street, #46
Fax: 212-928-0373
Phone: 617-359-6531

April 19, 2003

Susan J. Walker, M.D.
Acting Division Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Dear Dr. Walker

This is in response to your letter of April 7, 2003. We would like to address these issues you mentioned in that letter.

The animal studies included in the notification do not allow a calculation of the actual intake of the ingredients by the test animals and are therefore non-contributory to a safety evaluation. Furthermore, the patent information submitted indicates that the formulation may not always have the same number and/or quantity of ingredients.

We clearly indicated the ratio of each ingredient to whole amount of formulation in the first letter of September 9, 2002. All ingredients applied to the animal tests and patients were exactly followed these ratios. Here we provide the calculation in all animal tests and explanation on quantity difference of *VasoCleaner* ™ used as a dietary supplement.

1. The actual intake of each ingredient in *Toxicological Test*: the maximal drug-tolerance dose is 11.04g /kg, which is 66.24 times the clinically effective dose. At that dosage, each ingredient taken by the mice is as follow:

   Radix Ginseng (Ginseng root, 5.88%), 0.65g/kg body weight.
   Radix Polygoni Multiflori (Fleece flower root, 17.65%), 1.95g/ kg body weight.
   Crataegi, Fructus (Crataegus hawthorn fruit, 17.65%), 1.95g/ kg body weight.
   Rhizoma Alismatis Orientalitis (Water plantain rhizome, alisma, 17.65%), 1.95g/ kg body weight.
   Radix et Rhizoma Rhei (Rhubarb root and rhizome, 8.83%), 0.97g/ kg body weight.
   Pollen Typhae (Cattail pollen, bulrush, 17.65%), 1.95g/ kg body weight.
   Sargassum (Seaweed, 8.83%), 0.97g/ kg body weight.
   Resina Ferulae (Chinese asafetida, 5.88%), 0.65g/ kg body weight.

2. The actual intake of *VasoCleaner* ™ in the chronic toxicity test in rats is categorized in three levels, which are the high dose (34.8g /kg body weight/day), the medium dose (25.6g/kg body weight/day), and the low dose (12.8g/kg body weight/day). The intake of each ingredient in the corresponding dosage group by rat is listed in the following table.

PanVital Inc **New York, NY 10032**
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	High dose (/kg body weight/day)	Medium dose (/kg body weight/day)	Low dose(/kg body weight/ day)
Radix Ginseng	*2.05*	*1.51*	*0.75*
Radix Polygoni Multiflori	*6.14*	*4.52*	*2.26*
Fructus Crataegi	*6.14*	*4.52*	*2.26*
Rhizoma Alismatis Orientalitis	*6.14*	*4.52*	*2.26*
Radix et Rhizoma Rhei	*3.07*	*2.26*	*1.13*
Pollen Typhae	*6.14*	*4.52*	*2.26*
Sargassum	*3.07*	*2.26*	*1.13*
Resina Ferulae	*2.05*	*1.51*	*0.75*

3. The actual intake is 5 ml of *VasoCleaner* ™ solution in the rabbit pharmacological research listed in Part III of **Section 3**. Totally, 10 g of *VasoCleaner* ™ was in aqueous solution for individual rabbit. The actual intake of each ingredient is calculated as follow:

Radix Ginseng (Ginseng root, 5.88%), 0.39g/ kg body weight/day.
Radix Polygoni Multiflori (Fleece flower root, 17.65%), 1.18g/ kg body weight/day.
Crataegi, Fructus (Crataegus hawthorn fruit, 17.65%), 1.18g/ kg body weight/day.
Rhizoma Alismatis Orientalitis (Water plantain rhizome, alisma, 17.65%), 1.18g/ kg body weight/day.
Radix et Rhizoma Rhei (Rhubarb root and rhizome, 8.83%), 0.59g/ kg body weight/day.
Pollen Typhae (Cattail pollen, bulrush, 17.65%), 1.18g/ kg body weight/day.
Sargassum (Seaweed, 8.83%), 0.59g/ kg body weight/day.
Resina Ferulae (Chinese asafetida, 5.88%), 0.39g/ kg body weight/day.

4. In the Clinical Trial of *VasoCleaner* ™ on hyperlipidemia and atherosclerosis (**Part II of Section 3**), patient was orally administered 6g of *VasoCleaner*™, twice a day. The total daily usage is 12g. However, considering it as a dietary supplement, not for patient treatment, we recommend 3g of *VasoCleaner*™, three times a day, total 9g for daily serving. This recommended amount as a dietary supplement is less than the amount as a patient treatment formulation. Furthermore, that recommended dose is much lower than those used in the Toxicological tests and the chronic toxicity experiments that we did on mice and rats. That is why the formulation seems does not always have the same number and/or quantity of ingredients.

For history of use, you state that your product has been used as a herbal preparation prescribed for hyperlipidemia and atherosclerosis. Research regarding this preparation is said to have been published in journals in China. However, translations of these articles are not included in accordance with 21CFR 190.6(b)(4).

In fact, **Section 5** of the documents we submitted on January 12, 2003 included both the translation and the original version of the article published in the Chinese journal: *Journal of Chinese Medicine.*

The other information submitted with your notification included very general commentaries on the safety and functional effects of components of the preparation and standards for each ingredient in the preparation as established by the Pharmacopoeia of the Peoples's Republic of China. None of this general information addresses the safety of the specific formulation that is the subject of this notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: NOV 12 2003

From: Interdisciplinary Scientist/Pharmacist , Division of Dietary Supplement Programs , Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: VasoCleaner

Firm: PanVital, Inc.

Date Received by FDA: 1/22/03

90-Day Date: 4/23/03

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Gloria Chang

P drive/ NDI/ NDI File Closeout/DDSP SOP closeout process...

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD

APR - 7 2003

Yan Liu, President
PanVital Inc.
725 West 172 Street
No 455
New York, NewYork 10032

Dear Mr. Liu:

This is in response to your notification dated January 12, 2003, you submitted pursuant to 21 U.S.C. 350b(a)(2) and 21 Code of Federal Regulations (CFR) Part 190.6 and received by the Food and Drug Administration (FDA) on January 22, 2003. On November 8, 2002, FDA sent a letter informing you that your original notification filed with FDA on September 11, 2002 did not comply with all the requirements of a new dietary notification specified in the Federal regulations at 21 CFR 190.6. FDA received an amendment to the original notification on November 25, 2002, to address the issues in FDA's letter of November 8, 2002. Additional information was submitted on January 22, 2003.

Your notification concerns the substances, Radix Ginseng (Ginseng root) 5.88%, Radix Polygoni Multiflori (Fleece flower root), 17.65%, Crataegi, Fructus (Crataegus hawthorn fruit), 17.65%, Radix et Rhizoma Rhei (Rhubarb root and rhizome), 8.83%, Pollen Typhae (Cattail pollen, bulrush), 17.65%, Resina Ferulae (Chinese asafetida), 5.88%, and Sargassum (Seaweed), 8.83%, under the tradename "VasoCleaner™", that you assert are new dietary ingredients. You indicated that the botanical ingredients are dried to powders and packaged either in a capsule dosage form or infusion granules of tea bags. Conditions of use recommended are: Infusion: one granule tea bag (3 grams) after each meal, 9 grams of total daily serving. Encapsulated: Take three capsules (0.75 grams) after each meal, 2.25 grams of total daily serving.

Under 21 U.S.C. 350b(a)(2), the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient is required to submit certain information to FDA at least 75 days before a new dietary ingredient or a dietary supplement containing it is introduced or delivered for introduction into interstate commerce. This information must include the basis on which the manufacturer or distributor has concluded that the new dietary ingredient or a dietary supplement containing the new dietary ingredient will reasonably be expected to be

safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the product's labeling, will reasonably be expected to be safe. If this requirement is not met, the new dietary ingredient or dietary supplement containing it may be deemed to be adulterated under 21 U.S.C. 342(f)(1)(B), because there is inadequate information to provide reasonable assurance that the new dietary ingredient or dietary supplement containing it does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your notification and has concerns about the evidence on which you rely to support your conclusion that your product, VasoCleaner™ containing the eight botanical ingredients, will be reasonably expected to be safe for the suggested or intended uses.

The animal studies included in the notification do not allow a calculation of the actual intake of the ingredients by the test animals and are therefore non-contributory to a safety evaluation. Furthermore, the patent information submitted indicates that the formulation may not always have the same number and/or quantity of ingredients.

For history of use, you state that your product has been used as a herbal preparation prescribed for hyperlipidemia and atherosclerosis. Research regarding this preparation is said to have been published in journals in China. However, translations of these articles are not included in accordance with 21 CFR 190.6(b)(4). The other information submitted with your notification included very general commentaries on the safety and functional effects of components of the preparation and standards for each ingredient in the preparations as established by the Pharmacopoeia of the People's Republic of China. None of this general information addresses the safety of the specific formulation that is the subject of this notification.

We note that under your conditions of uses for the target population you reference the terms "patients with atherosclerosis and/or hyperlipoproteinmia" and under the duration of use you use the terms "symptoms and diseases" and "for atherosclerosis patient" and " to hyperlipoproteinmia patients." Please be aware that under 21 U.S.C. 321(g)(1)(B), if a product is implicitly or expressly represented as being intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease, it may be subject to regulation under the drug provisions of the Act. Further, you can find information on claims that may be made in the labeling of dietary supplements pursuant to 21 U.S.C. 343(r)(6) in the final rule on structure/function claims published in the January 6, 2000 Federal Register (65 FR 1000).

Your notification will be kept confidential for 90 days from the date of its receipt. After, April 21, 2003, your notification will be placed on public display at FDA's Dockets Management Branch in docket number 95S-0316. Prior to April 21, 2003, you may wish to identify in writing specifically what information in your notification you believe is proprietary, trade secret or otherwise confidential.

If you have any questions concerning this matter, please contact Victoria Lutwak of my staff at (301) 436-2375.

Sincerely,

Susan J. Walker, M.D.
Acting Division Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

PanVital Inc **New York, NY 10032**
725 West 172 Street, #46
Tel: 212-928-0373

January 12, 2003

Felicia B. Satchell, Director
Division of Standards and labeling Regulations
Officer of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW.
Washington D.C. 20204

Dear Mrs. Satchell,

Subject: *PanVital*'s Notification of *VasoCleaner*^{TM}

We initiated the process of notifying FDA our new dietary supplement product, *VasoCleaner*^{TM}, on September 8, 2002 (refer to the *PanVital's* notification letter of Sep 8, 2002). Two months later, we received the first letter from FDA indicating that our notification was incomplete due to the several unidentified issues (refer to the FDA letter of Nov.13, 2002). We responded with a letter documented as the amendment to the original notification to further address above issues (refer to the letter of Nov. 21, 2002). The amendment was still regarded incomplete informed by FDA officer Gloria Chan (refer to the *PanVital's* Telephone Memo on Dec. 3, 2002). According to her suggestion, we hereby submit another set of material that will still act as the amendment to the original notification aiming to provide sufficient information on which FDA can evaluate the safety of *VasoCleaner*^{TM}.

Firstly, we would like to address the issue of identifying the new and old ingredient(s) in *VasoCleaner*^{TM}. *VasoCleaner*^{TM} consists eight ingredients: Radix Ginseng, Radix Polygoni Multiflori, Fructus Crataegi, Rhizoma Alismatis Orientalitis, Radix Rhizoma Rhei, Pollen Typhae, Resina Ferulae, and Sargassum. Although our market survey revealed that all of them have been used either individually or combined with other herbs in dietary supplements on the current US market (refer to Market Survey), we could not find an authorized source providing strong evidence to confirm that any of them has been used as a dietary supplement before October 15, 1994. Therefore, we hereby notify FDA that all of the ingredients will be regarded by us as new ingredients for the safety evaluation. All citations regarding the application and toxicity of each individual ingredient are provided in the file that renamed "Section 6 Safety Evidence for Individual Ingredient", which will be used to replace **Section 5** and **Appendix 7** in the original notification. Section 6 in the original notification will be renamed as Section 5.

Secondly, the language versions issue. In the original notification, we actually provided the English versions of the corresponding materials written in Chinese. We think that the order of the files in the original notification might cause some confusion, for example, we provided the English

version (**File# 5** in the original notification) of each ingredient standard established by the Pharmacopoeia of the People's Republic of China before its Chinese version (**File# 6** in the original notification) without adequate explanation.

Thirdly, the dosage issue. As being mentioned in the last letter, *VasoCleaner*^{TM} can be served in two forms: infusion granules and encapsulated herbal extracts. The daily serving of *VasoCleaner*^{TM} and the amount of each ingredient in the two forms are listed as follow:

Daily serving of *VasoCleaner*^{TM} in infusion granules: one granule tea bag (3grams) after each meal, 9 grams of total for daily serving.

The daily intake of each ingredient in infusion granules:

Radix Ginseng (Ginseng root), 0.53 g /day.
Radix Polygoni Multiflori (Fleece flower root), 1.59 g /day.
Fructus Crataegi (Crataegus hawthorn fruit), 1.59 g /day.
Rhizoma Alismatis Orientalitis (Water plantain rhizome), 1.59 g /day.
Radix et Rhizoma Rhei (Rhubarb root and rhizome), 0.79 g /day.
Pollen Typhae (Cattail pollen, bulrush), 1.59 g /day.
Resina Ferulae (Chinese asafetida), 0.53 g /day.
Sargassum (Seaweed), 0.79 g /day.

Daily serving of *VasoCleaner*^{TM} in the encapsulated: three capsules (0.75grams) after each meal, 2.25grams of total for daily serving. The encapsulated is for the patients who cannot tolerate herbal smells.

The amount of daily intake of each ingredient in the encapsulated:

Radix Ginseng (Ginseng root), 0.13 g/day
Radix Polygoni Multiflori (Fleece flower root), 0.40 g /day.
Fructus Crataegi (Crataegus hawthorn fruit), 0.40 g /day.
Rhizoma Alismatis Orientalitis (Water plantain rhizome), 0.40 g/day.
Radix et Rhizoma Rhei (Rhubarb root and rhizome), 0.20 g/day.
Pollen Typhae (Cattail pollen, bulrush), 0.40 g/day.
Resina Ferulae (Chinese asafetida), 0.13 g /day.
Sargassum (Seaweed), 0.20 g/day.

Fourthly, the copy issue about the materials submitted by us. We submitted one original notification and two photocopies in the initial notification. Two photocopies of the original notification were submitted with our first five amendment letters. Therefore, we think your division should have five complete sets of our old notification documents. For the convenience of your work, we include all the relevant materials, including the previous document we sent to FDA, this time. There are totally five complete sets of documents: one set of original document and four additional sets of photocopies. Therefore, the entire evaluation can be done by only using the documents we submit this time.

PanVital Inc **New York, NY 10032**
725 West 172 Street, #46
Tel: 212-928-0373

We highly appreciate your consideration. Please contact me if you have any more questions concerning this matter.

Respectfully,

Yanzhu Liu
President
PanVital Inc.

Encl. Notification documents: one set of original and four sets of photocopies
cc: Officer Gloria Chan

PanVital Inc **New York, NY 10032**
Department of R&D **725 West 172 Street**
Tel: 212-928-0373

Abbreviated Contents

PanVital Inc **New York, NY 10032**
Department of R&D **725 West 172 Street**
Tel: 212-928-0373

Telephone Memorandum

To: President Yanzhu Liu
From: Min Dong
Date: 12:15pm, Dec. 3, 2002
Subject: Telephone conversation with FDA officer Gloria Chan

FDA officer Gloria Chan called this morning and left a message. I called back 11:50am. In the telephone conversation, she mainly addressed the following issues regarding our submitted notification of *VassoCleaner*^{TM}:

1. Identify the new and old ingredient(s) in *VassoCleaner*^{TM}. For the old ingredient(s), offer evidence to prove that it (they) has (have) been used in dietary supplement before October 15, 1994. For the new gradient(s), citations regarding its (their) application and toxicity should be provided.
2. Any document provided which is written in language other than English, an English translation version should be supplied with the original version.
3. Daily dosage of each individual ingredient in *VasoCleaner*^{TM} should be identified.
4. Any submitted document should be in one original and four photocopies.

PanVital Inc **New York, NY 10032**
725 West 172 Street, #46
Tel: 212-928-0373

November 21, 2002

Felicia B. Satchell
Director
Division of Standards and labeling Regulations
Officer of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW.
Washington D.C. 20204

Dear Mrs. Satchell,

Notice is hereby given in respond to your letter-document dated November 13, 2002. In that document, you indicated that the notification we sent you concerning the dietary supplement with trade name *VasoCleaner* was incomplete due to the deficiencies in several identified issues. We would like to provide further information as an amendment to address those issues as follow:

Identify which specific ingredient(s) is/are new dietary ingredient(s):
The *VasoCleaner*^{TM}, which we intend to market as a new dietary supplement product, consists eight ingredients: Radix Ginseng, Radix Polygoni Multiflori, Crataegi, Fructus, Rhizoma Alismatis Orientalitis, Radix et Rhizoma Rhei, Pollen Typhae, Resina Ferulae, and Sargassum. After conducting a further research on the products under the category of dietary products containing herbal gradients on the current USA market, we here inform that none of the ingredients can be considered as a new dietary ingredient.

Sufficiently describe VasoCleaner^{TM} (e. g. identify the Latin binomial names of the botanicals(herbal ingredients) including the genus, species, and the author and any other known relevant properties of the ingredient(s):
The table below summarizes the needed information. Further information regarding other known relevant properties of the ingredient(s) was listed in the File 6 of Section 5 in the current Notification.

PanVital Inc New York, NY 10032
725 West 172 Street, #46
Tel: 212-928-0373

Latin name	Genus	Species (Botanical name)	Family	English name	Mandarin name	Author
Radix Ginseng	*Panax*	*Panax ginseng C. A. Mey*	*araliaceae*	*ginseng root*	*ren shen*	*Divine Husbandman's Classic of the Materia Medica*
Radix Polygoni Multiflori	*Polygoni Multiflori*	*Polygonum multiflorum Thunb.*	*polygonaceae*	*Fleeceflower root*	*Shou wu*	*Materia Medica of RI Hua-Zi*
Fructus Crataegi	*Crataegi*	*Crataegus pinnatifida Bge.*	*rosaceae*	*Hawthorn fruit, crataegus*	*Shan zha*	*Supplement to the Extension of the Materia Medica*
Rhizoma Alismatis Orientalitis	*Alismatis Orientalitis*	*Alisma Plantago-aquatica L. var. orientale Samuels*	*Alismataceae*	*Water plantain rhizome, alisma*	*Ze xie*	*Divine Husbandman's Classic of the Materia Medica*
Radix et hizoma Rhei	*Rhizoma Rhei*	*Rheum palmatum L.*	*polygonaceae*	*Rhubarb root and rhizome*	*Da huang*	*Divine Husbandman's Classic of the Materia Medica*
Pollen Typhae	*Typhae*	*Typha angustifolia L.*	*Typhaceae*	*Cattail pollen, bulrush*	*Pu huang*	*Divine Husbandman's Classic of the Materia Medica*
Resina Ferulae	*Ferulae*	*Ferula sinkiangensis K. M. Shen*	*Umbelliferae*	*Chinese asafetida*	*Awei*	*Tang Materia Medica*
Herba Sargassii	*sargassum*	*Sargassum pallidum(Turn.) C. Ag.*	*sargassum*	*Seaweed*	*Hai zao*	*Divine Husbandman's Classic of the Materia Medica*

Include full reference citations in accordance with section 190.6(b)(4) that states that any reference to published information including abstracts, books, etc. shall be accompanied by reprints or photostatic copies of such references. If any part of the material is in a foreign language, there shall be an accurate and complete English translation.

We here make a clarification based on our current understanding of the Dietary Supplement Health and Education Act of 1994 (DSHEA) and the knowledge learned from your Division. We believe that although *VasoCleaner*^{TM} is a new form of dietary supplement, there is no new gradient in it. And none of them has not been chemically altered, when they used in dietary supplement. Therefore, we are not required by the law to provide FDA all reference citations to every ingredient. So Section 7 in current notification should be eliminated.

Include the specific serving level amounts (e.g. in mg, etc) per serving and total daily serving levels, include the target population if any, and any excluded subpopulation (e.g. pregnant or lactating women, or children, etc).

Serving levels:

Infusion granules: one granule tea bag (3grams) after each meal, 9 grams of total daily serving.

Encapsulated: three capsules (0.75grams) after each meal, 2.25grams of total daily serving. The encapsulated is for the patients who could not tolerate to herb smell.

Target population: patients with atherosclerosis and/or hyperlipoproteinmia.

Excluding subpopulation: pregnant and lactating women, and children.

Include if any, duration of use or limitations of use (e.g. use for 30 days), or if for chronic use or if there is no limitation, state this

PanVital Inc **New York, NY 10032**
725 West 172 Street, #46
Tel: 212-928-0373

The duration of using our product depends on the symptoms and diseases of the patients. The suggested duration follows: two-month to one-year for atherosclerosis patients, one-month to one-year to hyperlipoproteinmia patients.

We highly appreciate your consideration. Please contact me if you have any more questions concerning this matter.

Sincerely yours,

Yanzhu Liu
President
PanVital Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Washington, DC

NOV 8 2002

Yanzhu Liu, President
PanVital Inc., Distributor
725 West 172 Street, #46
New York, New York 10032

Dear Mr. Liu:

This is to inform you that the notification, dated September 8, 2002, you submitted pursuant to 21 U.S.C. 350b(a)(2) was received and filed by the Food and Drug Administration (FDA) on September 11, 2002. Your notification concerns the substances, Radix Ginseng (Ginseng root) 5.88%, Radix Polygoni Multiflori (Fleece flower root), 17.65%, Crataegi, Fructus (Crataegus hawthorn fruit), 17.65%, Radix et Rhizoma Rhei (Rhubarb root and rhizome), 8.83%, Pollen Typhae (Cattail pollen, bulrush), 17.65%, Resina Ferulae (Chinese asafetida), 5.88%, and Sargassum (Seaweed), 8.83%, under the tradename "VasoClean™", that you assert are new dietary ingredients. You indicated that the herbal ingredients are dried to powders and packaged either in a capsule dosage form or infusion granules of teabags. Conditions of use recommended are: Infusion: Take one bag after each meal, Encapsulated: Take three capsules after each meal. The maximum daily intake are: nine capsules each time, three times a day in the directions for use, or three bags of infusion, three times a day. You also included statements of nutritional support claims as follows:

"Ideal supplement for clearing bad lipids, and for improving vessel protective function"
"Keep your cholesterol levels healthy"
"Maintain healthy cholesterol levels"
"Keep your LDL and total cholesterol in a healthy range."

The law at 21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor of a dietary supplement that contains a new dietary ingredient submit certain information to FDA at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce. This information must include the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will

Another option is to send us at any time a new notification, in triplicate, that is complete and fully complies with 21 CFR 190.6. The date that we receive the additional information for either an amended or new notification is considered the new filing date. Please indicate in the cover letter if it is an amended or new notification.

Although not required, if you decide to submit an amended or new notification, we would appreciate your sending us an additional two copies for a total of five copies (i.e., an original and four copies) to facilitate our internal administrative processing of the notification. Please make sure that all copies you send us contain the same information in accordance with 21 CFR 190.6.

Your notification will be kept confidential for 90 days from the date of the effective filing date. After the 90-day period, your notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notification will not be disclosed to the public. Prior to the 90-day period, you may wish to identify in writing specifically what information you believe is proprietary in your current notification for FDA's consideration. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notification should be redacted before it is posted at Dockets.

For your information, the following FDA Internet sites and their corresponding links may be useful:

http://www.cfsan.fda.gov/~dms/supplmnt.html
http://www.cfsan.fda.gov/~lrd/fr97923e.html (21 CFR 190.6)

Please contact me at (301) 436-2371, if you have any questions concerning this matter.

Sincerely yours,

Felicia B. Satchell

Felicia B. Satchell
Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

PanVital Inc **New York, NY 10032**
725 West 172 Street, #46
Tel: 212-928-0373

Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW.
Washington D.C. 20204

September 8, 2002

Dear Food and Drug Administration:

Pursuant to the requirement of section 413 (a) (2) of the Federal Food, Drug and Cosmetic Act for Dietary Supplement, we wish to notify the Food and Drug Administration that we intend to market a new dietary supplement product, *VasoCleaner*™, a herb preparation, on the U.S. market 75 days after this notice. Please review this supportive information for considering safe the new dietary supplement listed below.

Distributor name:
PanVital Inc.

Address:
725 West 172 Street, #46
New York, NY 10032

The new dietary supplement *VasoCleaner*™ contains the following herbal ingredients. The level of each ingredient:

Radix Ginseng (Ginseng root), 5.88%
Radix Polygoni Multiflori (Fleece flower root), 17.65%
Crataegi, Fructus (Crataegus hawthorn fruit), 17.65%
Rhizoma Alismatis Orientalitis (Water plantain rhizome, alisma), 17.65%
Radix et Rhizoma Rhei (Rhubarb root and rhizome), 8.83%
Pollen Typhae (Cattail pollen, bulrush), 17.65%
Resina Ferulae (Chinese asafetida), 5.88%
Sargassum (Seaweed), 8.83%

Manufacturing process:
The herb ingredients are plant's root, seed, or fruit. They are extracted with water and alcohol, and then dried to powders. The powders are packed in two presentations, which are capsules and infusion granules of tea bags.

The conditions of use recommended:
Infusion: Take one bag after each meal.
Encapsulated: Take three capsules after each meal.
Maximum daily intake: Nine capsules each time, three times a day in the direction for use, or three bags of infusion, three times a day.

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The total daily intake of each dietary ingredient is less than 20% of the established safe dose recommended by the Pharmacopoeia of the People's Republic of China and other documents.

The history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended in the labeling of the dietary supplement, will reasonably be expected to be safe. The supporting studies and published articles include:

1. The history of use.
2. Toxicological tests of *VasoCleaner*™ in mice and rats (**File# 1**).
3. Pharmacological effectiveness and safety data on hyperlipidemia and atherosclerosis (AS) both in patients and dietary-induced rabbits (**File# 2**).
4. Documents of a China Patent describing the herbal formulation with both English translation (**File# 3**) and original version (**File# 4**).
5. Documents of each ingredient standard established by the Pharmacopoeia of the People's Republic of China, which are provided with both English (**File# 5**) and Chinese (**File# 6**) versions.
6. Published scientific articles describing the use possible mechanism of *VasoCleaner*™ (**File # 7,8,9).**
7. Other evidence of safety establishing that every ingredient will reasonably be expected to be safe (**Appendix 1-7).**

The statements of nutritional support read as follows:

"Ideal supplement for clearing bad lipids, and for improving vessel protective function"
"Keep your cholesterol levels healthy"
"Help to keep cholesterol levels in a normal range"
"Maintain healthy cholesterol levels"
"Keep your LDL and total cholesterol in a healthy range".

These statements will be accompanied by the required disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

We appreciate your timely response to acknowledge the receipt of this notice. Please also provide us a written confirmation that the above stated claims and labeling is in compliance with the Dietary Supplement Health and Education Act of 1994. Thank you very much for your cooperation.

Respectfully

Yanzhu Liu
President
PanVital Inc.